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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,293	05/07/2001	Robert Falotico	CRD-0931	2210

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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/850,293	FALOTICO, ROBERT	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated August 29, 2003. Claims 1-14 are pending. Claim 15 has been cancelled.

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 8 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendments have changed the scope of the claim; thus, a new rejection has been applied.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. in US Patent No. 6,214,901 in view of Morris et al. in US Patent No. 5,516,781.

Regarding claims 1 and 8, Chudzik et al. disclose a method/drug delivery device for preventing/treating constrictive vascular remodeling via a controlled delivery, by release from a stent, of a compound in therapeutic dosage amounts in the range from about thirty-five micrograms per fifteen millimeters of stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent, the compound substantially reducing in-lesion lumen loss both proximate and distal

to the stent, the compound being incorporated in a polymeric matrix, as recited in column 1, lines 20-32, lines 42-46, lines 55-60, column 3, lines 1-46, column 5, lines 6-26 and lines 60-62. Column 3, lines 1-3 recites, "the composition comprises a bioactive agent in combination with a plurality of polymers..." and column 5, lines 45-50, recites "The coating composition can also be used to coat stents...." Further, column 5, lines 58-62 states a range of about 0.05 mg to about 10 mg of bioactive agent per cm^2 of the gross surface of the device.

Given a stent range of 15-18 mm, this equates to

(0.05 mg/cm^2) * (15 –18 mm or 1.5-1.8 cm) = 0.075 mg to 0.090 mg

This equals 75 ug to 90 ug, which falls within the range of 35-435 ug, as claimed.

However, Chudzik et al. do not explicitly recite, a compound having anti-proliferative and anti-inflammatory properties. On the other hand, Morris et al. teach the use of rapamycin which is known for its anti-proliferative and anti-inflammatory properties. Therefore, it would be obvious to one with ordinary skill in art to have the bioactive agent/compound of Chudzik et al. be rapamycin for the purpose of its superior properties as an anti-proliferative and anti-inflammatory for treating vascular remodeling. Further, this would fall within the scope of bioactive agents described in column 5, lines 7-26 of Chudzik et al.

Regarding claims 2 and 9, further utilizing the compound to block proliferation of fibroblasts in a vascular wall in response to injury, thereby reducing a formation

of vascular scar tissue would necessarily occur as a result of coating a stent with rapamycin in the dosages as described by Chudzik et al. with rapamycin as taught by Morris et al.

Regarding claims 3 and 10, Morris et al. teach rapamycin as discussed above with regard to claim 1.

Regarding claims 4 and 11, a compound that is analogs and cogeners that bind a high-affinity cytosolic protein, FKBP12, and possess pharmacologic properties equivalent to rapamycin, is also taught by Morris et al. as discussed with regard to claim 1 above.

Regarding claims 5 and 12, further utilizing the compound to affect a translation of certain proteins involved in a collagen formation or metabolism would necessarily occur as a result of coating a stent with rapamycin in the dosages as described by Chudzik et al. with rapamycin as taught by Morris et al.

Regarding claims 6 and 13, Morris et al. teach rapamycin as discussed above with regard to claim 1.

Regarding claims 7 and 17, a compound that is analogs and cogeners that bind a high-affinity cytosolic protein, FKBP12, and possess pharmacologic properties

equivalent to rapamycin, is also taught by Morris et al. as discussed with regard to claim 1 above.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/850,233. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/850,507. Although the conflicting claims are not identical,

they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 09/850,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 09/850,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/575,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,585,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700